UNITED STATES PATENT AND TRADEMARK OFFICE

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MAY 18 2006

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

In re U.S. Patent No. 6,489,346
Application for Patent Term Extension for: ZEGERID® (omeprazole)

Dear Ms. Axelrad:

The United States Patent and Trademark Office (PTO) has received your letter of February 24, 2006 concerning the above-referenced application for patent term extension under 35 U.S.C. § 156.

PTO records indicate that the subject application for patent term extension was filed on August 12, 2004, and not August 17, 2004 as indicated in your letter. Because the New Drug Application (NDA) was approved on June 15, 2004, the submission of the application for patent term extension is timely within the meaning of 35 U.S.C. § 156(d)(1).

A notice of final determination of ineligibility for patent term extension was mailed on August 30, 2004. However, on February 28, 2005, applicant filed a reply arguing that the '346 patent should be entitled to patent term extension. First, applicant argued that the '346 patent is eligible because the enteric coated, delayed-release omeprazole of PRILOSEC®, covered by a previously-extended patent, has different properties and is therefore a different active ingredient than the omeprazole of ZEGERID® covered by the '346 patent. Second, applicant argued that the patent covering ZEGERID® was entitled to patent term because the NDA for ZEGERID® was submitted under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, while approval of prior omeprazole-containing products was sought under sections 505(b)(1) and 505(j). Applicant's position is that these are different provisions of law, and that the section 505(b)(2) approval of ZEGERID® is the first under that provision of law, thus permitting extension of the '346 patent as provided in 35 U.S.C. § 156(5)(A).

As for the first argument, the position of the PTO as stated in the letter of October 25, 2005 is that under *Pfizer, Inc. v. Dr. Reddy's Laboratories*, 359 F.3d 1361 (Fed. Cir. 2004), if the rights derived from the extension of a patent based upon the regulatory approval of an active ingredient encompass other compounds within the same active moiety, then extension based upon subsequent approvals of other compounds having the same active moiety must be barred.

The assistance of your Office is requested with regard to the second argument. Please advise the PTO as to whether the approval of the product identified in the application, ZEGERID® (omeprazole), was the first permitted commercial marketing or use of any active ingredient thereof *under the provision of law under which regulatory review occurred.* (35 U.S.C. 156(a)(5)(A)).

Telephone inquiries regarding this communication should be directed to Kathleen Kahler Fonda at (571)272-7754.

Kery A. Fries

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